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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/557,907	04/21/00	HORTON H	1530.0060004

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EXAMINER	
WILSON,M	
ART UNIT	**PAPER NUMBER**
1633	8

DATE MAILED: 06/20/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/557,907	HORTON ET AL.	
	Examiner	Art Unit	
	Michael Wilson	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 April 2000* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-103* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims *1-103* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-50, 52-56, 58-64, 66-75, 77-87, 89-94 and 96-103 drawn to methods of treating cancer using DNA encoding INF-ω, INF-α, INFτ, INF-β, IL-2, IL-1, IL-4, IL-7, IL-12, IL-15, IL-18 or GM-CSF, pharmaceutical compositions comprising DNA encoding INF-ω, and a kit, classified in class 514, subclass 44, et al.

II. Claims 51-55, 57-63, 65-74, 76-86, 88-93 and 95-103 drawn to a methods of treating cancer using mRNA encoding IFN-ω, IFNγ, IFNβ, IL-1, IL-4, IL-7, IL-12, IL-15, IL-18, GM-CSF, classified in class 514, subclass 44.

The inventions are distinct, each from the other because of the following reasons:

Groups I and II are patentably distinct because the DNA has a patentably distinct mode of action than RNA and requires a different search. The protocols and reagents required to work with DNA are materially distinct and separate than those required for RNA. The method of using the DNA is not required for the method of using the RNA and the method of using the RNA is not required for the method using DNA.

2. Claims 1-8, 35-51, 59-103 are generic to a plurality of disclosed patentably distinct species comprising IFN-ω, INF-α, INF-τ, IFNγ, IFNβ, IL-1, IL-2, IL-4, IL-7, IL-12, IL-15, IL-18, GM-CSF or a combination thereof. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. Overall, the cytokines claimed are

patentably distinct because they have different functions *in vivo* and have different modes of operation in treating cancer.

If applicants elect IFN-ω, claims 1-14, 23-28, 35-41, 43-50, 52-103 encompass IFN-ω and would be examined as they relate to the elected invention. If applicants elect IFN-α, claims 1-8, 15-18, 29-41, 43-50 and 52-103 encompass IFN-α and would be examined as they relate to the elected invention. If applicants elect IL-2, claims 1-8, 19-22, 35-41, 43-50 and 52-103 encompass IL-2 and would be examined as they relate to the elected invention. If applicants elect a combination of cytokines, claims 1-8, 35-50 and 52-103 could encompass at least two cytokines, and applicants should elect the specific combination of cytokines for examination. If applicants elect INF-τ, IFNγ, IFNβ, IL-1, IL-4, IL-7, IL-12, IL-15, IL-18 or GM-CSF, generic claims 1-8, 35-41, 43-51, 59-103 would be examined as they related to the elected invention.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

No claim is allowed.

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-0120.

Questions of formal matters can be directed to the patent analyst, Tracey Johnson, who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-2982.

Questions of a general nature relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

If attempts to reach the examiner, patent analyst or Group receptionist are unsuccessful, the examiner's supervisor, Deborah Clark, can be reached on (703) 305-4051.

The official fax number for this Group is (703) 308-4242.

Michael C. Wilson

MICHAEL C. WILSON
PATENT EXAMINER